

UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA,
ALBANY DIVISION

CAROLYN PARKER,

Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION,

Defendant.

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CASE NO.: _____

**COMPLAINT FOR DAMAGES
AND JURY DEMAND**

Plaintiff, CAROLYN PARKER (“Plaintiff”), files this Complaint and for causes of action against Defendant Boston Scientific (the “Defendant”), and alleges as follows:

INTRODUCTION

1. On or about July 30, 2020, at Phoebe Putnam Memorial Hospital in Albany, Georgia, Plaintiff CAROLYN PARKER was surgically implanted with the Boston Scientific Advantage Fit™ transobturator mid-urethral sling (the “Advantage Fit” or the “pelvic mesh product”), a pelvic mesh product and medical device designed, manufactured, and marketed by Defendant.

2. Although the Advantage Fit was intended to treat stress urinary incontinence, neither Plaintiff nor her healthcare providers were warned that the Advantage Fit was defective and negligently designed and marketed. As a result of being surgically implanted with Defendant’s unreasonably dangerous defective Advantage Fit pelvic mesh product, Plaintiff has suffered, and continues to suffer, debilitating injuries, as described further herein. In addition and in the alternative, Plaintiff suffered from pre-existing injuries/conditions which were aggravated, exacerbated, and/or accelerated by implantation of the Advantage Fit device. Plaintiff brings this suit for damages related to those injuries.

JURISDICTION AND VENUE

3. The Court has jurisdiction over this civil action pursuant to 28 U.S.C. § 1332(a) inasmuch as the amount in controversy exceeds \$75,000 and the Plaintiff is a citizen of a different state than the Defendant.

4. Venue in this district for pretrial proceedings in these civil actions is proper under 28 U.S.C. § 1391, inasmuch as a substantial part of the events or omissions giving rise to the claim occurred in this district. Specifically, Petitioner was implanted with the product at issue in this district at Phoebe Putnam Memorial Hospital in Albany, Georgia, and was injured in this district.

5. Defendant is subject to *in personam* jurisdiction in the U.S. Middle District Court of Georgia because Defendant placed defective products in the stream of commerce and all or some of those products were implanted into and caused personal injuries to Petitioner, a Georgia resident, in the State of Georgia. Each Defendant has sufficient minimum contacts in Georgia or otherwise intentionally avails itself of the Georgia market through, without limitation, its advertisement, promotion, marketing, sales and/or distribution and other business activities, so as to render the exercise of jurisdiction over it by the Georgia courts consistent with traditional notions of fair play and substantial justice.

PARTIES

6. Plaintiff CAROLYN PARKER is, and was at all times relevant to this suit, a citizen and resident of Leesburg, Georgia.

7. Defendant Boston Scientific Corporation is a Massachusetts corporation with its principal place of business in Massachusetts. At all times material hereto, Boston Scientific was engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce throughout the United States,

either directly or indirectly, its medical devices intended to treat stress urinary incontinence and/or pelvic organ prolapse, including the Advantage Fit product that was implanted into Plaintiff.

8. Defendant is vicariously liable for the acts and omissions of its employees and/or agents who were at all times relevant hereto acting on behalf of the Defendant and within the scope of its employment or agency with the Defendant.

9. At all times relevant herein, the Defendant was engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, testing, training, marketing, promoting, packaging, labeling, and/or selling such devices, including the Advantage Fit Pelvic Mesh Product. Defendant manufactures, markets, advertises, promotes, and sells products worldwide.

FACTUAL BACKGROUND

The Pelvic Mesh Products

10. At all times relevant herein, Defendant was engaged in the business of developing, designing, licensing, manufacturing, distributing, marketing, packaging, labeling, advertising, delivering, selling and introducing into interstate commerce, including within the United States and within the State of Georgia, either directly or indirectly through third parties or related entities, a line of pelvic mesh products (the “Pelvic Mesh Products”), including the Advantage Fit mesh product, the device implanted into Plaintiff. The Advantage Fit product was designed primarily for the purpose of treating stress urinary incontinence. All references herein to Pelvic Mesh Products includes the Advantage Fit pelvic mesh product.

11. Stress urinary incontinence (“SUI”) is a type of incontinence characterized by leakage of urine during moments of physical stress, such as coughing, laughing, or sneezing.

Although inconvenient, SUI is not life-threatening. At all relevant times, the Advantage Fit was intended to be used, and for Plaintiff was used, to treat stress urinary incontinence.

12. Surgical mesh is a medical device that is generally used to repair weakened or damaged tissue. This is the type of mesh used in Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse (POP) or to support the urethra to treat SUI. Most pelvic mesh products, including the Advantage Fit, are comprised of non-absorbable, synthetic, monofilament polypropylene mesh. Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh products, were and are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma, and minimal pain while correcting SUI and POP.

13. Pelvic mesh products used for the surgical management of SUI in women are primarily three different designs: the transobturator sling, the retropubic sling, and the single-incision or "mini sling." The Advantage Fit sling is a retropubic sling.

14. Prior the implantation of the Advantage Fit pelvic mesh product at issue in this claim, Defendant sought and obtained Food and Drug Administration ("FDA") approval to market the Advantage Fit under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

15. In 1996, the FDA cleared the first pelvic mesh products for use in the treatment of SUI. These products include products manufactured, marketed, and distributed by Defendant.

These products were and are approved by the FDA under the abbreviated 510(k) approval process. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to these pelvic mesh products, including the Advantage Fit pelvic mesh product at issue in this case.

16. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff and others is biologically incompatible with human tissue, and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh Products.

17. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response, and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh. Certain information was available in the medical literature regarding the dangers of polypropylene mesh and manufacturers should have been aware of this literature.

1. Shrinkage and bacteria lead to an evolving process and increased erosion (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449).
2. Polypropylene mesh has long been known to shrink (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound

Obstetrics Gynecol 2007; 29:449). By 1998, polypropylene mesh was known to shrink 30-50%. This was subsequently confirmed in 2007 (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449). Predominate infection/inflammation was noted in 2007 in explanted polypropylene samples (Yahi Y. Int Urogyn J 2007; 18(Suppl 1):S149).

3. The weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages (Osterberg B. ActaChirScand1979; 145:431, Merritt K. J BiomatAppl 1991; 5:185, An Y. J Biomed Mater Res (ApplBiomat) 1998; 43:338).
4. The large surface area promotes wicking of fluids and bacteria which provides a safe haven for bacteria which attach themselves to the mesh during the insertion process (Mahmoud W. J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).
5. The size of the mesh placed equates to a large surface area with many places for bacteria to hide while being protected from host defenses (Mahmoud W. J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).
6. Polypropylene is impure: There is no such thing as pure polypropylene. Polypropylene contains about 15 additional compounds which are leached

from the polypropylene and are toxic to tissue which enhances the inflammatory reaction and the intensity of fibrosis (Sternschuss G. J Urol 2012; May 12 epub, Frostling H. Scand J Work Environ Health 1984; 10:163).

7. Prolene (polypropylene) was shown to be not inert in 1986 and again in 2003 with flaking and fissuring demonstrated by scanning electron microscopy which leads to degradation and release of toxic compounds. This enhances the inflammatory and fibrotic reactions (Coda A. Hernia 2003; 7:29, Jongebloed WL. Doc Ophthalmol 1986; 64:143–52).
8. With the loss of polypropylene due to degradation, the surface area is greatly increased thus providing greater areas for bacterial adherence and more elution of toxic compounds from the polypropylene and also the freed toxic polypropylene itself, all of which increases the inflammatory reaction and intensity of fibrosis (Jongebloed W. Doc Ophth 1986; 64:143, Sternschuss G. J Urol 2012; May 12 epub, Clave A. Int Urogyn J 2010; 21:261).
9. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia [painful sexual intercourse]. Cosson, M., et al., Mechanical properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int Urogynecol J Pelvic Floor Dysfunct, 2003. 14(3): p. 169-78; discussion 178. Jones, K.A., et al.,

Tensile properties of commonly used prolapse meshes. *Int Urogynecol J Pelvic Floor Dysfunct*, 2009. 20(7): p. 847-53. Margulies, R.U., et al., Complications requiring reoperation following vaginal mesh kit procedures for prolapse. *Am J Obstet Gynecol*, 2008. 199(6): p. 678 e1-4.

10. Erosion can be defined as the mesh wearing, or slowly grinding through the vaginal wall. This is a serious complication and moreover, there is evidence that meshes shrink in vivo leading to increased stiffness, pain and poor restoration of the normal properties of the vagina. Dora, C.D., et al., Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery. *J Urol*, 2004. 171(5): p. 1970-3.
11. Larger pores within polypropylene mesh materials, allowing macrophage and leukocyte migration, reduce infection. Birch C, Fynes MM. The role of synthetic and biological prosthesis in reconstructive pelvic floor surgery. *Curr Opin Obstet Gynecol*. 2002; 14:527–595. 22. Govier FE, Kobashi KC, Kozlowski PM, Kuznetsov DD, Begley SJ, McGonigle KF, et al. High complication rate identified in sacrocolpopexy patients attributed to silicone mesh. *J Urol*. 2005;65:1099–1103.

18. Defendant used Marlex® HGX-030-01 Polypropylene Homopolymer resin in its transvaginal mesh kits, both pelvic organ prolapse kits and sling systems. The Marlex® resin was manufactured by Phillips Sumika Polypropylene Company, (“Phillips”) a joint venture between Chevron Phillips Chemical Company, LP, and Sumitomo Chemical.

19. Marlex HGX-030-01 resin is a polypropylene plastic that comes in the form of pellets. For several years, Phillips issued revised Material Safety Data Sheets (“MSDS”) for Marlex polypropylene. Defendant was aware of the Marlex MSDS at all relevant times, including when it manufactured and marketed its Products to the public, including Plaintiff and her physicians.

20. The Marlex MSDS expressly prohibits use of the material for permanent human implantation:

MEDICAL APPLICATION CAUTION: DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL MATERIAL IN MEDICAL APPLICATIONS INVOLVING PERMANENT IMPLANTATION IN THE HUMAN BODY OR PERMANENT CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.

DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL COMPANY LP MATERIAL IN MEDICAL APPLICATIONS INVOLVING BRIEF OR TEMPORARY IMPLANTATION IN THE HUMAN BODY OR CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES UNLESS THE MATERIAL HAS BEEN PROVIDED DIRECTLY FROM CHEVRON PHILLIPS CHEMICAL COMPANY LP UNDER AN AGREEMENT WHICH EXPRESSLY ACKNOWLEDGES THE CONTEMPLATED USE.

CHEVRON PHILLIPS CHEMICAL COMPANY LP MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OF THIS MATERIAL FOR USE IN IMPLANTATION IN THE HUMAN BODY OR IN CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.

21. When the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case, are inserted in the female body according to the manufacturers’ instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

22. On October 1, 2004, Phillips Sumika Polypropylene Company (PSPC) entered a one-year stand-alone indemnification/insurance agreement which waived the company’s liability for Boston Scientific’s decision to use the polypropylene material in medical applications. That

agreement included the following language for Boston Scientific's use of the resin material in its transvaginal mesh products:

BEFORE USING ANY PSPC POLYPROPYLENE PRODUCT, BOSTON SCIENTIFIC IS ADVISED AND CAUTIONED TO MAKE ITS OWN DETERMINATION AND ASSESSMENT OF THE SAFETY AND SUITABILITY OF THE PSPC POLYPROPYLENE PRODUCT FOR USE BY, FOR OR ON BEHALF OF BOSTON SCIENTIFIC. IT IS THE ULTIMATE RESPONSIBILITY OF BOSTON SCIENTIFIC TO ENSURE THAT THE PSPC POLYPROPYLENE PRODUCT IS SUITED TO BOSTON SCIENTIFIC'S SPECIFIC APPLICATION.

23. The 2004 Indemnity Agreement placed the burden on Boston Scientific to conduct any and all necessary testing to ensure that the product it marketed with Marlex resin was safe for its intended use.

24. Subsequent to this 2004 indemnity agreement, in September of 2005, Phillips decided not to renew its contract with Boston Scientific because the resin was not intended for use in permanent implant devices. Per the terms of the 2004 contract between the two companies, Boston Scientific decided to exercise a right it held to make a "last-time" buyout before the contract was terminated. In 2005, BSC purchased 4,000 pounds of Marlex® HGX-030-01, the equivalent of a 10-year supply.

25. Synthetic materials like polypropylene, including that used by Defendant, are known to induce an acute inflammatory response, followed by chronic inflammatory response and foreign-body reaction. A chronic inflammatory response and heightened foreign body reaction have the potential to result in failure of the device to perform safely and effectively, with significant adverse consequences for the patient. Further, a prolonged inflammatory response exposes the polypropylene mesh to a continuous bath of oxidants that may cause in vivo degradation of the mesh.

26. The polypropylene MSDS specifies that polypropylene may react with strong oxidizing agents. Despite the known warnings and complications, Defendant utilized Marlex that had never been qualified by the supplier for permanent human implantation for a medical application that was disallowed according to the Material Safety Data Sheet (MSDS) in its manufacture of the Advantage Fit sling.

27. The polypropylene mesh used by Defendant for its Pelvic Mesh Products also contracts as a result of the development of scar tissue exacerbated by the foreign body reaction. Polypropylene mesh is known to shrink by up to over 50% during healing. When the transvaginal mesh shrinks during the normal healing process, the arms of the mesh pull on its anchoring points in the pelvic sidewall muscles, tending to pull these anchoring points and the attached muscle toward the midline. In women with these transvaginal mesh implants, including Plaintiff herein, this pulling on the pelvic sidewall muscles causes pain at rest, during sexual intercourse, during defecation, and during normal daily activities like coughing, jumping and straining. This aggravated pulling will cause new or worsening pain to the women in whom the product is implanted. In addition, it is well established that nerves can become entrapped as a result of the chronic inflammatory response and fibrosis surrounding the mesh.

28. Defendant marketed the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product, to the medical community and to patients as safe, effective, and reliable medical devices that can be implanted by safe, effective, and minimally invasive surgical techniques.

29. Defendant marketed and sold the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product, through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies included, but are not limited to, aggressive marketing and the provision of valuable cash and non-cash benefits to healthcare providers. Defendant also

utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of this product.

30. Contrary to the representations and marketing of Defendant, the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product, have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating revision surgeries, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff. The defects stem from many issues, including:

- a. the use of polypropylene material in the Pelvic Mesh Products and the immune reaction that results;
- b. the design of the Pelvic Mesh Products to be inserted transvaginally into an area of the body with high levels of pathogens that adhere to the mesh, which can cause immune reactions and subsequent tissue breakdown;
- c. the contraction or shrinkage of the mesh;
- d. biomechanical issues with the design of the mesh that creates strong amounts of friction between the mesh and the underlying tissue that subsequently causes that tissue to degrade;
- e. the use and design of anchors in the Pelvic Mesh Products that when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;
- f. degradation of the mesh itself over time which causes the internal tissue to degrade;
- g. the welding of the mesh itself during production, which creates a toxic substance that contributes to the degradation of the mesh and host tissue; and

- h. the design of the retropubic sling calls for placement medial to the arcus tendinous which is not reliable when following the IFU, which places the tape into the obturator internus muscle and levator muscles in a substantial minority of retropubic slings leading to an increased risk of pain.

31. Upon information and belief, Defendant has consistently underreported and withheld information about the propensity of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product, to fail and cause injury and complications, and have misrepresented the efficacy and safety of these products, through various means and media, actively and intentionally misleading the public.

32. Despite the chronic underreporting of adverse events associated with the Pelvic Mesh Products, enough complaints were recorded for the Food and Drug Administration (“FDA”) to issue a public health notification regarding the dangers of these devices. On October 20, 2008, the FDA issued a Public Health Notification that described over a thousand (1,000) complaints (otherwise known as “adverse events”) that had been reported over a three-year period relating to the Pelvic Mesh Products and other similar products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA’s MAUDE database indicates that Defendant is one of the manufacturers of the products that are the subject of the notification.

33. On July 13, 2011, the FDA issued a Safety Communication entitled, “UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse.” Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded that surgical mesh used in transvaginal repair of pelvic organ prolapse was an area of **“continuing serious concern”** (emphasis added). The FDA concluded that serious complications associated

with surgical mesh for transvaginal repair of pelvic organ prolapse were “not rare.” These serious complications include, but are not limited to, neuromuscular problems, vaginal scarring/shrinkage, and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of pelvic organ prolapse and stress urinary incontinence with mesh-kits was more effective than traditional non-mesh repair of these conditions. The FDA conducted a systematic review of the published scientific literature from 1996 to 2011 and concluded that transvaginal pelvic organ prolapse repair with mesh “does not improve symptomatic results or quality of life over traditional non mesh repair.” In the July 13, 2011, Safety Communication, the FDA concluded that “a mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient’s quality of life. Complete removal of mesh may not be possible.” The information contained in the FDA’s Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011, was known or knowable to Defendant and was not disclosed in any manner.

34. In September 2011, the FDA acknowledged the need for additional data and noted in “Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence” that the literature and information developing on SUI repair with mesh “indicates that serious complications can occur...[and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI.”

35. After the 2011 FDA notification that mesh complications from POP repairs were “not rare,” a 2013 article was published that stated: “as outlined in the FDA notifications, patients

should be forewarned that some transvaginal mesh complications are life altering and might not always be surgically correctable. Furthermore, that study noted that "the women who received both MUS and TM represented a complicated surgical group. Fifteen women (43%) required MUS takedown concurrently with prolapse mesh excision. Two-thirds of these women had associated chronic pelvic pain and vaginal pain, in addition to its urinary symptoms."

36. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating: There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh...Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

37. Plaintiff's injuries, as will be more fully established in Discovery, are of the type reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

38. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

39. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the White Paper). In the White Paper, the

FDA noted that the published, peer-reviewed literature demonstrates that “[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh.”

40. The FDA White Paper further stated that, “these products are associated with serious adverse events...compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair.”

41. In its White Paper, the FDA advises doctors to, inter alia, “[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications.” The FDA concludes its White Paper by stating that it “has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse.”

42. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it “has NOT seen conclusive evidence that using transvaginal placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risk.

43. On April 16, 2019, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of anterior compartment prolapse (cystocele) to stop selling and distributing its products immediately. In fact, the FDA has determined that the manufacturers, Boston Scientific and Coloplast specifically, have not demonstrated reasonable assurance of safety and effectiveness for these devices, which is the premarket standard that now applies to them since the agency reclassified them into class III (high risk) in 2016.¹

¹ www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants (last visited 10/14/2021).

44. Boston Scientific knew known about the Pelvic Mesh Products' risks and complications identified in the FDA Safety Communication, ACOG/AUGS Joint Committee Opinion, and the FDA Advisory that addressed the sales of transvaginal mesh implants for pelvic organ prolapse.

45. Defendant has further known the following:

- a. that some of the predicate devices for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices;
- b. that there were and are significant differences between the Pelvic Mesh Products and some or all of the predicate devices, rendering them unsuitable for designation as predicate devices;
- c. that these significant differences render the disclosures to the FDA incomplete and misleading; and
- d. that the Pelvic Mesh Product was and is causing numerous patients' severe injuries and complications.

46. Defendant suppressed this information and failed to accurately and completely disseminate or share this and other critical information with others, including Plaintiff. As a result, Defendant actively and intentionally misled and continues to mislead the public into believing that the Pelvic Mesh Products and the procedures for implantation were and are safe and effective.

47. Defendant failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products. Defendant did not, and has not, adequately studied the extent of the risks associated with its Pelvic Mesh

Products.

48. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendant, as it generated the directions for use, created the procedures for implanting the device, and trained the implanting physicians.

49. Defendant provided incomplete, insufficient, and misleading training and information to physicians to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increase the sales of these products.

50. The injuries, conditions, and complications suffered by women who have been implanted with the Pelvic Mesh Products include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, acute and chronic nerve damage and pain, obturator nerve damage/neuralgia, pudendal nerve damage/neuralgia, ilioinguinal nerve damage/neuralgia, pelvic floor damage, myofascial pain, chronic pelvic/extrapelvic pain, urinary and fecal incontinence, and prolapse of organs. In many cases, these women have been forced to undergo intensive medical treatment, including, but not limited to, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

51. The medical and scientific literature studying the effects of polypropylene pelvic mesh (like the material used in the Pelvic Mesh Products) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

52. Defendant knew and had reason to know that the Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

53. At all relevant times herein, Defendant continued to promote the Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long or short-term efficacy.

Defective Design

54. The design of the retropubic sling calls for placement medial to the arcus tendinous which is not reliable when following the IFU, which places the tape into the obturator internus muscle and levator muscles in a substantial minority of retropubic slings leading to an increased risk of pain. Defendant failed to study or account for this issue when designing the device.

55. The Pelvic Mesh Products were designed to be permanently implanted into a woman's body yet the product changes after implantation; it contracts over time which can pull or compress nerves important for sexual function, mobility, bowel function, bladder function, and chronic pelvic and nerve pain (neuralgia). This contraction over time, which can pull, and also cause fibrosis of muscles, muscle spasms, adhesions between tissues, and inflammation which impair sexual function, impaired mobility, impaired bowel and bladder function, and chronic pelvic pain, neuralgia, among other mesh-related issues.

56. Moreover, despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair,

polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue herein. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

57. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction."

58. Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, were and are unreasonably susceptible to degradation and fragmentation inside the body, shrinkage or contraction inside the body, intense foreign body reaction, chronic inflammatory response, chronic wound healing, chronic infections in and around the mesh fibers, and nerve entrapment in the collagen scar formation. Defendant knew or should have known of these serious risks and should have, therefore, warned physicians and patients regarding these risks to the extent they were known or knowable.

59. To this day, the Advantage Fit pelvic mesh product continues to be marketed to the medical community and to patients as safe, effective, and reliable medical devices, implanted by safe, effective, and minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments and other competing products.

60. Defendant knew or should have known that its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue in this case, unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendant began marketing the Advantage Fit, Defendant was aware that the Advantage Fit was associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication.

61. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, and advertised, promoted, marketed, sold and distributed the its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, as safe medical devices when Defendant knew or should have known that the Pelvic Mesh Products were not safe for its intended purposes, and that the products would cause, and did cause, serious medical problems, and in many patients, including Plaintiff, catastrophic injuries. Further, while some of the problems associated with the Pelvic Mesh Products, including the Advantage Fit pelvic mesh product, were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

62. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, its Pelvic Mesh Products, including the Advantage Fit pelvic mesh

product at issue, have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

63. Further, Defendant failed to design and establish a safe, effective procedure for removal of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh products at issue, or to determine if a safe, effective procedure for removal of the Pelvic Mesh Products exists. Thus, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Pelvic Mesh Products.

64. Feasible, reasonable, and suitable alternative designs as well as reasonable suitable alternative procedures and instruments for repair of stress urinary incontinence have existed at all times relevant to this matter, including, but not limited to the following: the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Repliform or other biological matrix; a sling with larger pore, lighter weight mesh and less polypropylene such as Ultrapro; a sling with larger pore, lighter weight mesh such as the mesh used in the Ethicon Prolift+M transvaginal mesh device; a sling made of Polyvinylidene fluoride (PVDF); a retropubic mini-sling, such as the TFS Surgical retropubic mini sling; a retropubic mini-sling made of PVDF, such as the DynaMesh®SIS device; or a retropubic mini-sling comprised of Ultrapro or other larger pore, lighter weight mesh.

65. The specific nature of defects for Defendant's Advantage Fit pelvic mesh product at issue in this case include, but are not limited to, the following:

A. The use of polypropylene in the Pelvic Mesh Products and the adverse tissue reactions

and host defense response that result from such material, causing adverse reactions and serious, permanent injuries including, but not limited to, painful recurrent erosions and associated intractable pain;

- B. The design of the Advantage Fit to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;
- C. The use and design of a trocar and anchors in the Advantage Fit sling, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;
- D. The design of the retropubic sling calls for placement medial to the arcus tendinous which is not reliable when following the IFU, which places the tape into the obturator internus muscle and levator muscles in a substantial minority of retropubic slings leading to an increased risk of pain;
- E. Biomechanical issues with the design of the Advantage Fit which results in a non-anatomic condition leading to contraction or shrinkage of the mesh inside the body, that in turn causes surrounding tissue to become eroded, inflamed, fibrotic and infected, resulting in serious and permanent injury;

- F. The propensity of the mesh design characteristics of the Advantage Fit mesh for plastic deformation when subjected to tension both during implantation and once implanted inside the body which causes the mesh, or portions thereof, to be encapsulated in a rigid scar plate which leads to nerve entrapment, bacterial entrapment, tissue destruction, enhanced inflammatory and fibrotic response and chronic pain;
- G. The propensity of the mesh used in the Advantage Fit mesh to become rigid and inflexible, causing it to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where the product is implanted, and causing discomfort and pain with normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);
- H. The propensity of the mesh used in the Advantage Fit for degradation or fragmentation over time, which causes an increased surface area that leads to enhanced chronic inflammatory and fibrotic reaction, causes a “barbed wire” or “saw blade” effect by the fragmented surface “sawing” through the tissue, leads to bacteria harboring in the fragmented, peeled and split fiber surface which in turn leads to chronic infections at the mesh surface, and results in continuing injury over time; and
- I. The inability of surgeons to effectively treat many of these conditions due to the integration of the mesh into the pelvic tissue and thus the inability to safely remove or excise the mesh once a complication occurs.

Failure to Warn/Inadequate Warnings & Instructions

66. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put the Plaintiff, her treating physicians, and the public on notice of

the dangers and adverse effects caused by implantation of the Pelvic Mesh Products.

67. The Advantage Fit is also defective due to Defendant's failure to adequately warn or instruct Plaintiff and/or her health care providers after the product left the manufacturer and before and after implantation of the Advantage Fit pelvic mesh product of subjects including, but not limited to, the following:

- A. The Pelvic Mesh Products' propensities, including the Advantage Fit product, to contract, retract, and/or shrink inside the body;
- B. The Pelvic Mesh Products' propensities, including the Advantage Fit product, for degradation, fragmentation and/or migration;
- C. The Pelvic Mesh Products', including the Advantage Fit product, inelasticity preventing proper mating with the pelvic floor and vaginal region;
- D. The frequency and manner of transvaginal mesh erosion or extrusion resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- E. The risk of chronic inflammation resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- F. The risk of chronic infections resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- G. The risk of permanent vaginal or pelvic scarring resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- H. The risk of de novo urinary dysfunction resulting from the Pelvic Mesh Products, including the Advantage Fit product;

- I. The risk of de novo dyspareunia or painful sexual intercourse resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- J. The risk of recurrent, intractable pelvic/extrapelvic pain and other pain resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- K. The risk of obturator nerve irritation/obturator neuralgia resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- L. The risk of pudendal nerve irritation/pudendal neuralgia resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- M. The risk of ilioinguinal nerve irritation/ilioinguinal neuralgia resulting from the Pelvic Mesh Products, including the Advantage Fit product;
- N. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products, including the Advantage Fit product, which in some cases is not feasible nor possible;
- O. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Products, including the Advantage Fit product;
- P. Treatment of stress urinary incontinence with Defendant's Advantage Fit Pelvic Mesh Product is no more effective than feasible, available and safer alternatives;
- Q. Treatment of stress urinary incontinence with Defendant's Advantage Fit Pelvic Mesh Product exposes patients to greater risk than feasible, available and safer alternatives;
- R. Treatment of stress urinary incontinence with the Advantage Fit Pelvic Mesh Product makes future surgical repair more difficult than feasible, available and safer alternatives;

- S. Use of the Pelvic Mesh Products, including the Advantage Fit product, puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;
- T. Removal of the Pelvic Mesh Products, including the Advantage Fit product, due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;
- U. Complete removal of the Pelvic Mesh Products, including the Advantage Fit product, may not be possible and may not result in complete resolution of the complications, including pain; and
- V. The nature, magnitude, and frequency of the complications that could arise as a result of implantation of the Pelvic Mesh Products, including the Advantage Fit product; and
- W. The Pelvic Mesh Products' defects and hazards described herein.

68. Defendant underreported and continues to underreport information about the propensity of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the Pelvic Mesh Products through various means and media.

69. Defendant underreported and continues to underreport information about the propensity of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, to fail and to cause injury and complications and have made unfounded representations regarding the efficacy and safety of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, through various means and media.

70. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue.

71. The Advantage Fit pelvic mesh product at issue was at all times utilized and implanted in a manner intended and/or foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

72. Defendant knowingly provided incomplete and insufficient training and information to physicians regarding the use of its Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, and the aftercare of patients implanted with those Pelvic Mesh Products.

73. At all relevant times herein, Defendant continued to promote its products as safe and effective even when no clinical trials had been done supporting long-term or short-term efficacy or safety. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with its Pelvic Mesh Products, including the magnitude and frequency of these risks.

74. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put Plaintiff, the medical community, Plaintiff's treating physicians, and the general public on notice of the dangers and adverse effects caused by implantation of the Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue.

75. Defendant's Pelvic Mesh Products, including the Advantage Fit pelvic mesh product at issue, as designed, manufactured, distributed, sold and/or supplied by Defendant, were

defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

76. The risk of serious injuries was known or should have been known to Defendant, but in spite of these risks, Defendant continued to market the Advantage Fit pelvic mesh product for transvaginal use to physicians and patients, including Plaintiff and Plaintiff's healthcare providers, without adequate warnings.

Resulting Injury from Defendant's Pelvic Mesh Products

77. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with Defendant's Pelvic Mesh Products include, but are not limited to: erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, obturator nerve damage/neuralgia, pudendal nerve damage/neuralgia, ilioinguinal nerve damage/neuralgia, pelvic floor damage, chronic pelvic/extrapelvic pain, emotional distress and mental anguish, and other debilitating complications. In addition, affected women, including Plaintiff, will need to be continuously monitored because of being implanted with Defendant's Pelvic Mesh Products.

78. In many of these cases, including that of the Plaintiff, women have had or will have to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia. Removal of contracted, eroded and/or infected transvaginal mesh can require multiple surgical interventions for removal of mesh

and results in scarring on fragile compromised pelvic tissue and muscles.

79. The medical and scientific literature studying the effects of pelvic mesh products, like that of the Advantage Fit pelvic mesh product implanted in Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the pelvic mesh products.

Plaintiff's Advantage Fit Implantation

80. Upon information and belief, Thomas Talley, M.D. recommended the Advantage Fit pelvic mesh product to Plaintiff as appropriate and safe for the treatment of her stress urinary incontinence. Consequently, Plaintiff consented to the implantation of the Advantage Fit pelvic mesh product.

81. On or about July 30, 2020, Plaintiff underwent surgery to address her stress urinary incontinence with Thomas Talley, M.D., at Phoebe Putney Memorial Hospital in Albany, Georgia. During this surgery, she was implanted with a Boston Scientific Advantage Fit sling, identified as follows:

Implants:			
Implant		Qty Used	Qty Wasted
SYS FIT ADVANTAGE [114147]		1	
Manufacturer	BOSTON SCIENTIFIC CORP	Surgeon	
Lot Number	24870264	Talley, Thomas Carter, MD	
Catalog Number	M0068502110		
Expiration Date	12/03/22		

82. The Advantage Fit pelvic mesh product implanted in Plaintiff was in the same or substantially similar condition as it was when it left Defendant's possession, and in the condition directed by and expected by Defendant.

83. Plaintiff and her physician foreseeably used and implanted the Advantage Fit pelvic mesh product properly and appropriately and did not misuse or alter these products in an

unforeseeable manner.

84. Neither Plaintiff nor her healthcare providers were warned that the Advantage Fit pelvic mesh product was unreasonably dangerous or of the risks of the Pelvic Mesh Products, outlined herein, even when used exactly as intended by Defendant. To the contrary, Defendant promoted and sold the type of transvaginal mesh devices implanted in Plaintiff and thousands of women like Plaintiff, to healthcare providers as a safe alternative to other procedures that did not incorporate the Defendant's products.

85. On October 21, 2021, Plaintiff underwent a transvaginal sling revision procedure with Dr. Jessica Hammett at Emory Healthcare, as well as a subsequent procedure with Dr. Dionysios Veronikis, M.D. on May 9, 2022, in order to attempt relief for Plaintiff's vaginal pain, groin pain, leg pain, and dyspareunia caused by Defendant's Advantage Fit sling.

86. As a direct and proximate cause of having the Advantage Fit pelvic mesh device implanted in her, Plaintiff has experienced significant physical injuries and mental and physical pain and suffering, including obturator neuralgia, pudendal neuralgia, pelvic pain, extrapelvic pain, groin pain, leg pain, dyspareunia, nerve pain, recurrence of incontinence, urinary problems, has undergone a revision/repair procedure and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

87. As a direct and proximate result of being surgically implanted with Defendant's unreasonably dangerous Advantage Fit pelvic mesh product, Plaintiff has suffered, and continues to suffer, debilitating injuries, including but not limited to the injuries listed above and, likely, nerve pain that may be permanent. In addition and in the alternative, Plaintiff suffered from pre-existing injuries/conditions which were aggravated, exacerbated, and/or accelerated by

implantation of the Advantage Fit device. Plaintiff brings this suit for damages related to those injuries.

DISCOVERY RULE AND TOLLING

88. Plaintiff realleges and incorporates by reference paragraphs 1 through 87 of this Complaint as if each were set forth fully and completely herein.

89. To the extent further pleading be necessary, Plaintiff asserts all applicable contractual, state statutory, and/or common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

90. Plaintiff could not have reasonably discovered her injuries and/or the occasion, manner and/or means by which Defendant's breach of duty occurred until within two years of the filing of this complaint. Further, Plaintiff did not and, exercising reasonable diligence, including consultation with medical professionals, could not discover the existence of her legal cause of action or the injuries caused by Defendant's breach of duty and/or defective products until within three years of the filing of this complaint.

91. Moreover, Defendant continues to deny that its products are defective or cause injuries such as those suffered by Plaintiff and Defendant continued to manufacture and sell the products at issue and/or related or predicate products. Any applicable statute of limitations has been tolled due to equitable tolling by the knowing and active concealment, affirmative misrepresentations, and denial of material facts known by Defendant when Defendant had a duty to disclose and/or by the application of the discovery rule. As a result of Defendant's fraudulent concealment, Plaintiff and her healthcare providers were unaware, and could not have known or

have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of Defendant.

COUNT I
Negligence

92. Plaintiff adopts by reference paragraphs 1 through 91, each inclusive, as though fully set forth herein.

93. Boston Scientific directly or indirectly negligently manufactured, designed, tested, researched and developed, labeled, packaged, distributed, promoted, marketed, advertised, and sold its Pelvic Mesh Products across the United States and in the state of Georgia, including the Advantage Fit implanted into Plaintiff.

94. At all times material hereto, Boston Scientific had a duty to Plaintiff to exercise reasonable care in the design, manufacture, research and development, testing, processing, advertising, marketing, labeling, packaging, distribution, promotion and sale of its Pelvic Mesh Products. Defendant had a duty to exercise reasonable and ordinary care in the design, development, manufacture, testing, labeling, packaging, distribution, marketing, and/or sale of the Advantage Fit so as to avoid exposing others to foreseeable and unreasonable risks of harm.

95. Defendant breached its duty of care to Plaintiff and her physicians in the design, development, manufacture, testing, labeling, packaging, distribution, marketing, and sale of the Advantage Fit.

96. Defendant breached its duty in that it failed to warn Plaintiff and her physicians by not reporting the risk of serious defects and life-altering complications described herein that Defendant knew or should have known were associated with the Advantage Fit prior to the time of Plaintiff's implantation.

97. Defendant also breached its duty by receiving and failing to warn of complaints or adverse events regarding the Advantage Fit to the public and the medical community.

98. Plaintiff was a foreseeable user of the Advantage Fit.

99. Defendant knew women like Plaintiff would be implanted with the Advantage Fit.

100. Defendant knew or should have known that the Advantage Fit's defective condition made the device unreasonably dangerous or likely to be unreasonably dangerous when used in its intended or reasonably foreseeable manner.

101. At the time of the manufacture and sale of the Advantage Fit, Defendant knew or should have known that the Advantage Fit was designed and manufactured in such a manner so as to present an unreasonable risk of harm.

102. The Advantage Fit was unreasonably dangerous when used by Plaintiff's physician, who followed the instructions provided by Defendant and used Advantage Fit according to its instructions.

103. At the time Advantage Fit left Defendant's possession, the device was in a condition that made it unreasonably dangerous to Plaintiff.

104. At the time Plaintiff was implanted with the Advantage Fit, the device was in a condition that made it unreasonably dangerous.

105. The Advantage Fit used by Plaintiff was expected to and did reach Plaintiff and her treating physician without substantial change in the condition in which the device was designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold by Defendant.

106. At all relevant times, Plaintiff's physician used the Advantage Fit in the manner in which was the device was intended.

107. As designers, developers, manufacturers, inspectors, advertisers, packagers, distributors, and suppliers of Advantage Fit, Defendant had superior knowledge of the product and owed a duty of care to Plaintiff.

108. Boston Scientific breached its duty and was negligent in its actions, misrepresentations, and omissions toward Plaintiff in the following ways:

- a) Failing to test its Pelvic Mesh Products in a reasonable manner in order to ascertain whether or not it was safe and proper for the purpose for which it was designed, manufactured, labeled, promoted and sold;
- b) Failing to utilize and implement a reasonably safe design in the manufacture of its Pelvic Mesh Products;
- c) Failing to manufacture its Pelvic Mesh Products in a reasonably safe condition;
- d) Failing to warn Plaintiff or Plaintiff's health care providers of the risk of chronic, disabling pain, nerve injury/irritation, and other adverse risk and complications from the use of its Pelvic Mesh Products when used as instructed;
- e) Failing to remove its Pelvic Mesh Products from the market when Boston Scientific knew the risks outweighed the benefits;
- f) Failing to accurately and completely warn Plaintiff and Plaintiff's health care providers of the accurate risks and benefits of its Pelvic Mesh Products; and
- g) Manufacturing its Pelvic Mesh Products, which are unreasonably dangerous and defective when used as instructed.

109. Boston Scientific knew or should have known that its Pelvic Mesh Products had unreasonably dangerous risks and caused serious injuries and complications of which Plaintiff and Plaintiff's health care providers would not be aware.

110. It was foreseeable that Defendant's misrepresentations, actions, and omissions would cause severe, permanent, and debilitating injuries to Plaintiff.

111. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

112. As a direct and proximate result of the negligent actions and inactions of Boston Scientific as set forth above, Plaintiff sustained injuries including, but not limited to obturator neuralgia, pudendal neuralgia, pelvic pain, extrapelvic pain, vaginal pain, groin pain, leg pain,

dyspareunia, urinary issues, pain and suffering, mental anguish, loss of capacity for the enjoyment of life, physical disfigurement, physical impairment, and loss of earning capacity.

113. WHEREFORE, Plaintiff demands judgment of Boston Scientific for damages as described herein in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT II
Negligence—Design Defect

114. Plaintiff realleges and incorporates by reference paragraphs 1 through 113 of this Complaint as if each were set forth fully and completely herein.

115. At all times relevant, Defendant was in the business of designing, developing, manufacturing, testing, labeling, packaging, distributing, marketing, and/or selling Advantage Fit, including the Advantage Fit that were inserted into Plaintiff.

116. Defendant had a duty to exercise reasonable and ordinary care in the design, development, manufacture, testing, labeling, packaging, distribution, marketing, and/or sale of Advantage Fit so as to avoid exposing others to foreseeable and unreasonable risks of harm.

117. Defendant breached its duty of care to Plaintiff and her physicians in the design, development, testing, labeling, packaging, distribution, marketing, and sale of the Advantage Fit.

118. Plaintiff's implanting physician was a foreseeable user of Advantage Fit.

119. Defendant knew women like Plaintiff would be implanted with the Advantage Fit.

120. Defendant knew or should have known that Advantage Fit's defective condition made the drug unreasonably dangerous.

121. The Advantage Fit was unreasonably dangerous when used by Plaintiff, who followed the instructions provided by Defendant and used Advantage Fit according to its common usage.

122. At the time Advantage Fit left Defendant's possession, the device was in a condition that made it unreasonably dangerous to Plaintiff.

123. At the time Plaintiff was implanted with the Advantage Fit, the device was in a condition that made it unreasonably dangerous.

124. The Advantage Fit used by Plaintiff was expected to and did reach Plaintiff without substantial change in the condition in which the drug was designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold by Defendant.

125. At all relevant times, Plaintiff used Advantage Fit in the manner in which was the drug was intended.

126. As designers, developers, manufacturers, inspectors, advertisers, packagers, distributors, and suppliers of the Advantage Fit, Defendant had superior knowledge of the product and owed a duty of care to Plaintiff.

127. Defendant failed to exercise reasonable and due care under the circumstances and therefore breached its duty of care to Plaintiff in the following ways:

- a. Failing to design the Advantage Fit in a manner that protected Plaintiff from injury;
- b. Designing and distributing a product in which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking measures to reduce or avoid harm;
- c. Designing and distributing a product in which it knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other drugs available for the same purpose;
- d. Failing to use reasonable care to warn or instruct Plaintiff, Plaintiff's healthcare providers, or the general healthcare community about Advantage Fit's substantially dangerous condition or about facts making the product likely to be dangerous, including pre- and post-sale;
- e. Failing to perform reasonable pre- and post-market testing of Advantage Fit to determine whether the product was safe for its intended use;

- f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would recommend, use, insert, and remove Advantage Fit;
- g. Advertising, marketing, and recommending the use of Advantage Fit, while concealing and failing to disclose or warn of the dangers known by Defendant to be connected with and inherent in the use of Advantage Fit;
- h. Representing that Advantage Fit was safe for its intended use when, in fact, Defendant knew and should have known the product was not safe for its intended purpose;
- i. Continuing manufacture and sale of Advantage Fit with the knowledge that Advantage Fit was dangerous and not reasonably safe;
- j. Failing to use reasonable and prudent care in the design, research, and development of Advantage Fit so as to avoid the risk of serious harm associated with the use of the device;
- k. Failing to establish and maintain an adequate post-marketing surveillance program for Advantage Fit;
- l. Failing to adequately and correctly report safety information relative to Advantage Fit product resulting in inadequate warnings;
- m. Failing to provide adequate and continuous warnings about the inherent danger of breakage of the Advantage Fit product;
- n. Failing to warn Plaintiff and her physicians by not reporting the risk of serious defects and life-altering complications described above;

128. It was foreseeable that Defendant's misrepresentations, actions, and omissions would cause severe, permanent, and debilitating injuries to Plaintiff.

129. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

130. As a direct and proximate result of Defendant's negligence, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT III
Negligence— Failure to Warn

131. Plaintiff adopts and incorporates by reference paragraphs 1 through 130 above.

132. Boston Scientific researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its Pelvic Mesh Product, and in the course of same, directly promoted or marketed the products to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of its Pelvic Mesh Product.

133. Plaintiff's use of the Pelvic Mesh Product was entirely foreseeable to Boston Scientific. Boston Scientific expected and intended patients like Plaintiff to use its products all the while knowing its products were defective and would cause serious harm.

134. The Pelvic Mesh Product was defective and unreasonably dangerous when it left the possession of Boston Scientific in that the product contained warnings and directions which were misleading and were inadequate and insufficient to alert the physicians and consumers, such as Plaintiff, to the dangerous risks and complications associated with the Pelvic Mesh Product, including, but not limited to chronic, disabling pain, nerve injury/irritation, and other adverse risk and complications like those suffered by Plaintiff.

135. Defendant knew or reasonably should have known that Advantage Fit was dangerous or likely to be dangerous when used in its intended or reasonably foreseeable manner.

136. Defendant knew that the Advantage Fit could cause harm and failed to warn Plaintiff of this potential injury.

137. Defendant had a duty to warn Plaintiff, Plaintiff's physician, and/or the medical community of the potential for harm.

138. Defendant had a continuing duty to warn Plaintiff, Plaintiff's physician, and/or the medical community of the potential for harm.

139. At the relevant times, Defendant knew or should have known that Advantage Fit was designed and manufactured in such a manner as to present an unreasonable risk of harm.

140. Boston Scientific, one of the world's largest manufacturers, promoters, and sellers of pelvic mesh products, is held to the level of knowledge of an expert in the field, and further, Boston Scientific had knowledge of the dangerous risks and complications of its Pelvic Mesh Products of which it failed to warn Plaintiff, and/or protect Plaintiff by informing Plaintiff's health care providers.

141. Plaintiff and Plaintiff's health care providers did not have the same knowledge as Boston Scientific and no adequate warning was communicated to Plaintiff and/or Plaintiff's health care providers.

142. The Advantage Fit did not include an adequate warning that the Advantage Fit can cause serious injury to users.

143. Defendant failed to properly and/or adequately warn or instruct that Advantage Fit can cause serious injury to users.

144. Defendant also failed to properly and adequately warn and instruct Plaintiff and her healthcare providers with regard to the inadequate research and testing of Advantage Fit.

145. Defendant breached its duty to Plaintiff by failing to warn of the risks and dangers of using Advantage Fit as intended.

146. The warnings that accompanied the Advantage Fit failed to provide the level of information that an ordinary consumer and/or healthcare provider, would expect when using the product in a manner reasonably foreseeable to Defendant.

147. Had Plaintiff or her implanting physician received proper or adequate warnings and instructions as to the risks of using Advantage Fit, Plaintiff would have avoided the risk and could have obtained or used an alternative treatment for her stress urinary incontinence.

148. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

149. Boston Scientific had a continuing duty to warn consumers, including Plaintiff and Plaintiff's health care providers, of its Pelvic Mesh Product, and the risks and dangers associated with it, and negligently and/or wantonly breached its duty as follows:

- a. Failed to include adequate warnings and instructions/directions for use for its Pelvic Mesh Product that would alert consumers and consumer's health care providers to the dangerous risks and serious complications of its Pelvic Mesh Product.
- b. Failed to provide adequate post-marketing warnings and instructions after Boston Scientific knew or should have known of the significant risks of injury and complications associated with the use of the Pelvic Mesh Product.
- c. Failed to inform Plaintiff and Plaintiff's health care providers that the Pelvic Mesh Product had not been adequately and thoroughly tested for safety in certain classes of patients.

150. Boston Scientific deliberately concealed and/or intentionally withheld knowledge of the risks and/or complications of the Pelvic Mesh Product from Plaintiff, Plaintiff's health care providers, and the medical community. By so acting, Boston Scientific acted with conscious and deliberate disregard of the foreseeable harm caused by its Pelvic Mesh Product.

151. Although Boston Scientific knew, or was reckless in not knowing, of the defective nature of the Pelvic Mesh Product, it continued to promote the Pelvic Mesh Product aggressively, without providing adequate warnings and instructions concerning its use, so as to maximize sales

and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by these products.

152. As a direct and proximate result of the negligent actions and inactions of Boston Scientific as set forth above, Plaintiff sustained injuries including, but not limited to obturator neuralgia, pudendal neuralgia, pelvic pain, extrapelvic pain, vaginal pain, groin pain, leg pain, dyspareunia, urinary issues, pain and suffering, mental anguish, loss of capacity for the enjoyment of life, physical disfigurement, physical impairment, and loss of earning capacity.

153. WHEREFORE, Plaintiff demands judgment of Boston Scientific for damages as described herein in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT IV
Strict Liability—Failure to Warn

154. Plaintiff adopts and incorporates by reference paragraphs 1 through 153 above.

155. Boston Scientific researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce its Pelvic Mesh Product, and in the course of same, directly promoted or marketed the products to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of its Pelvic Mesh Product.

156. Plaintiff's use of the Pelvic Mesh Product was entirely foreseeable to Boston Scientific. Boston Scientific expected and intended patients like Plaintiff to use its products all the while knowing its products were defective and would cause serious harm.

157. The Pelvic Mesh Product was defective and unreasonably dangerous when it left the possession of Boston Scientific in that the product contained warnings and directions which were misleading and were inadequate and insufficient to alert the physicians and consumers, such

as Plaintiff, to the dangerous risks and complications associated with the Pelvic Mesh Product, including, but not limited to chronic, disabling pain, nerve injury/irritation, and other adverse risk and complications like those suffered by Plaintiff.

158. Boston Scientific, one of the world's largest manufacturers, promoters, and sellers of pelvic mesh products, is held to the level of knowledge of an expert in the field, and further, Boston Scientific had knowledge of the dangerous risks and complications of its Pelvic Mesh Products of which it failed to warn Plaintiff, and/or protect Plaintiff by informing Plaintiff's health care providers.

159. Plaintiff and Plaintiff's health care providers did not have the same knowledge as Boston Scientific and no adequate warning was communicated to Plaintiff and/or Plaintiff's health care providers.

160. Boston Scientific had a continuing duty to warn consumers, including Plaintiff and Plaintiff's health care providers, of its Pelvic Mesh Product, and the risks and dangers associated with it, and negligently and/or wantonly breached its duty as follows:

- d. Failed to include adequate warnings and instructions/directions for use for its Pelvic Mesh Product that would alert consumers and consumer's health care providers to the dangerous risks and serious complications of its Pelvic Mesh Product.
- e. Failed to provide adequate post-marketing warnings and instructions after Boston Scientific knew or should have known of the significant risks of injury and complications associated with the use of the Pelvic Mesh Product.
- f. Failed to inform Plaintiff and Plaintiff's health care providers that the Pelvic Mesh Product had not been adequately and thoroughly tested for safety in certain classes of patients.

161. Boston Scientific deliberately concealed and/or intentionally withheld knowledge of the risks and/or complications of the Pelvic Mesh Product from Plaintiff, Plaintiff's health care providers, and the medical community. By so acting, Boston Scientific acted with conscious and deliberate disregard of the foreseeable harm caused by its Pelvic Mesh Product.

162. Although Boston Scientific knew, or was reckless in not knowing, of the defective nature of the Pelvic Mesh Product, it continued to promote the Pelvic Mesh Product aggressively, without providing adequate warnings and instructions concerning its use, so as to maximize sales and profits at the expense of the public health and safety, in knowing, conscious, and deliberate disregard of the foreseeable harm caused by these products.

163. As a direct and proximate result of the negligent actions and inactions of Boston Scientific as set forth above, Plaintiff sustained injuries including, but not limited to obturator neuralgia, pudendal neuralgia, pelvic pain, extrapelvic pain, vaginal pain, groin pain, leg pain, dyspareunia, urinary issues, pain and suffering, mental anguish, loss of capacity for the enjoyment of life, physical disfigurement, physical impairment, and loss of earning capacity.

164. WHEREFORE, Plaintiff demands judgment of Boston Scientific for damages as described herein in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT V
Strict Liability—Defective Design

165. Plaintiff adopts and incorporates by reference paragraphs 1 through 164 above.

166. At all times material hereto, Boston Scientific engaged in the business of selling, distributing, manufacturing, marketing, labeling, and/or promoting its Pelvic Mesh Product, which was unreasonably dangerous, and therefore defective. The product was defective as labeled.

167. At all times material hereto, Boston Scientific's Pelvic Mesh Product reached Plaintiff without substantial change in the condition in which it left the possession of the Defendant and was used in manner which had been contemplated and labeled.

168. Boston Scientific's Pelvic Mesh Product was defective and unreasonably dangerous when it entered the stream of commerce and was received by Plaintiff because:

- a. When placed in the stream of commerce the Pelvic Mesh Product contained unreasonably dangerous design defects and were not reasonably safe as intended to be used, subjecting users and consumers like Plaintiff to risks which exceeded the benefits of the product;
- b. When placed in the stream of commerce, the Pelvic Mesh Product was defective in design and formulation, making the use of the product more dangerous than an ordinary consumer would expect and more dangerous than other devices/procedures used to surgically treat SUI;
- c. The Pelvic Mesh Product was insufficiently and inadequately tested;
- d. The Pelvic Mesh Product was unreasonably defective when used as intended especially in light of the fact that safer alternatives existed;
- e. The intended use of the Pelvic Mesh Product caused harmful side effects which outweighed any potential utility; and
- f. The Pelvic Mesh Product was marketed and promoted for use as a safe product, when it was not safe for its intended use.

169. As a direct and proximate result of the negligent actions and inactions of Boston Scientific as set forth above, Plaintiff sustained injuries including, but not limited to obturator neuralgia, pudendal neuralgia, pelvic pain, vaginal pain, groin pain, urinary issues, pain and suffering, mental anguish, loss of capacity for the enjoyment of life, physical disfigurement, physical impairment, and loss of earning capacity.

170. WHEREFORE, Plaintiff demands judgment from Boston Scientific for damages as described herein in an amount determined by the jury and such other and further relief as allowed in equity or law.

COUNT VI
Fraud & Deceit

171. Plaintiff realleges and incorporates by reference paragraphs 1 through 170 of this Complaint as if each were set forth fully and completely herein.

172. At all times relevant, Defendant intentionally or recklessly misrepresented the safety of Advantage Fit for its intended use.

173. Defendant knew or were reckless in knowing that its representations were false.

174. Defendant has falsely and fraudulently represented and continues to represent to the medical and healthcare community, Plaintiff and her physicians, and/or the public that Advantage Fit was safe when, in fact, Advantage Fit was unreasonably dangerous.

175. Defendant has falsely and fraudulently represented and continues to represent to the medical and healthcare community, Plaintiff and her physicians, and/or the public that the Advantage Fit had been appropriately tested and was found to be safe and effective.

176. The representations made by Defendant was, in fact, false. When Defendant made its representations, it knew and/or had reason to know that those representations were false, and it willfully, wantonly, and recklessly disregarded the inaccuracies in its representations and the dangers and health risks to users of Advantage Fit.

177. Defendant made these representations with the intent of defrauding and deceiving the medical community, Plaintiff, Plaintiff's physicians, and/or the public, and also inducing the medical community, Plaintiff, Plaintiff's physicians, and/or the public to recommend, prescribe, dispense, and purchase Advantage Fit for use as a form of treatment for stress urinary incontinence, all of which evidenced a callous, reckless, willful, and depraved indifference to the health, safety, and welfare of Plaintiff.

178. In reliance upon these false representations, Plaintiff and/or her physicians were induced to, and did use Advantage Fit, thereby causing Plaintiff's severe and permanent personal injuries and damages. Defendant knew or had reason to know that Plaintiff and her physicians and other healthcare providers had no way to determine the truth behind Defendant's concealment and omissions, which included material omissions of facts surrounding the use of Advantage Fit as described in detail herein.

179. Plaintiff and her physicians reasonably relied on facts provided by Defendant, who foreseeably and purposefully suppressed and concealed facts that were critical to understanding the real dangers inherent in the use of Advantage Fit.

180. Having knowledge based on Defendant's research and testing, or lack thereof, Defendant blatantly and intentionally distributed false information, including but not limited to assurances to Plaintiff, the public, and Plaintiff's healthcare providers and physicians, that the Advantage Fit was safe for use and was as safe or safer than other products and/or procedures available and/or on the market. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted, concealed, and suppressed the dissemination of certain results of testing and research to healthcare professionals, Plaintiff, her physicians, and the public at large.

181. Defendant had a duty—when disseminating information to the public—to disseminate truthful information, and a parallel duty not to deceive the public, Plaintiff, and/or her physicians.

182. The information distributed to the public, the medical community, Plaintiff, and her physicians by Defendant included, but was not limited to websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, professional literature, reports, press releases, advertising campaigns, television commercials, print advertisements, and/or other commercial media, and contained material representations that were false and misleading, as well as omissions and concealments of the truth about the dangers of the use of Advantage Fit.

183. These representations, and others made by Defendant, were false when made and/or were made with the pretense of actual knowledge when such knowledge did not actually exist and were made recklessly and without regard to the true facts.

184. Defendant recklessly and/or intentionally falsely represented the dangerous and serious health and safety concerns inherent in the use of Advantage Fit to Plaintiff, her physicians, and the public at large for the purpose of influencing the sales of products that Defendant knew to be dangerous and defective and/or not as safe as other alternatives.

185. At the time the representations were made, Plaintiff and her healthcare providers did not know the truth about the dangers and serious health and/or safety risks inherent in the use of Advantage Fit.

186. Plaintiff did not discover the true facts about the dangers and serious health and/or safety risks, nor did Plaintiff discover the false representations of Defendant, nor would Plaintiff with reasonable diligence have discovered the true facts about Defendant's misrepresentations at the time when Plaintiff used Advantage Fit.

187. Had Plaintiff known the true facts about the dangers and serious health and/or safety risks of Advantage Fit, neither Plaintiff nor her physicians would have purchased, used, or relied on Defendant's representations and omissions concerning Advantage Fit.

188. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

189. As a direct and proximate result of Defendant's fraud, Plaintiff have been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VII
Fraud by Omission

190. Plaintiff realleges and incorporates by reference paragraphs 1 through 189 in this Complaint as if each were set forth fully and completely herein.

191. At all times relevant, Defendant intentionally or recklessly misrepresented the safety of Advantage Fit for its intended use.

192. Defendant knew or was reckless in knowing that its representations were false.

193. In representations to Plaintiff and/or to her healthcare providers, Defendant fraudulently concealed and intentionally omitted the following material information:

- a. That Advantage Fit was not as safe as other products and procedures available to treat stress urinary incontinence;
- b. That the risk of adverse events with Advantage Fit was higher than with other products and procedures available to treat stress urinary incontinence;
- c. That Advantage Fit was not adequately tested;
- d. That the limited clinical testing for Advantage Fit revealed a higher risk of adverse events, above and beyond those associated with other products and procedures available for stress urinary incontinence;
- e. That Defendant deliberately failed to follow up on the adverse results from clinical studies and/or formal and informal reports from physicians and/or other healthcare providers and either ignored, concealed, and/or misrepresented those findings;
- f. That Defendant was aware of dangers of the Advantage Fit in addition to and above and beyond those associated with other products and procedures available for stress urinary incontinence;
- g. That Advantage Fit was defective, and that it caused dangerous and adverse side effects;
- h. That when Advantage Fit needed to be removed, the removal procedure could be impossible; and
- i. That Advantage Fit was designed negligently and designed defectively.

194. Defendant were under a duty to disclose the foregoing issues to Plaintiff.

195. Defendant had sole access to material facts concerning the defective nature of the products and its propensity to cause serious and dangerous side effects and, hence, cause dangerous injuries and damage to persons who used Advantage Fit, such as Plaintiff.

196. Defendant knew that Plaintiff could not determine the truth of this information.

197. Defendant's concealment and omissions of material facts concerning the safety of Advantage Fit were made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff, Plaintiff's physicians, surgeons, and healthcare providers and to induce them to purchase, prescribe, and/or dispense Advantage Fit and/or to mislead them into reliance upon and cause them to use Advantage Fit.

198. At the time these representations were made by Defendant, and at the time Plaintiff and/or her physicians used Advantage Fit, Plaintiff and/or her physicians were unaware of the falsehood of these representations and reasonably believed them to be true.

199. Defendant knew and had reason to know that Advantage Fit could and would cause severe and grievous personal injury to the users of the product and was inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

200. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

201. As a direct and proximate result of Defendant's fraudulent concealment and/or omissions, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT VIII
Negligent Misrepresentation

202. Plaintiff realleges and incorporates by reference paragraphs 1 through 201 of this Complaint as if each were set forth fully and completely herein.

203. Defendant had a duty to tell Plaintiff and the public the truth about the risks and harms associated with Advantage Fit.

204. Defendant had a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, her healthcare providers, and the public that Advantage Fit had been tested and found to be safe and effective for treatment of stress urinary incontinence.

205. At relevant times, Defendant breached that duty by providing Plaintiff, her healthcare providers, and the general medical community with false or incorrect information or omitted or failing to disclose material information concerning Advantage Fit, including, but not limited to, misrepresentations regarding the safety of Advantage Fit.

206. The information distributed by Defendant to the public, the medical community, Plaintiff, and her healthcare providers, including advertising campaigns, labeling materials, print advertisements, and commercial media, was false and misleading and contained omissions and concealment of truth about the dangers of Advantage Fit.

207. Defendant's intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff and Plaintiff's healthcare providers; to falsely assure them of the quality of Advantage Fit; and to induce the public and

medical community, including Plaintiff and her healthcare providers, to request, recommend, prescribe, insert, purchase, and continue to use Advantage Fit.

208. The representations made by Defendant was, in fact, false. Advantage Fit was not safe for human use in its intended and reasonably foreseeable manner. Use of Advantage Fit is dangerous, as there is a risk that it may break and cause serious injury.

209. In reliance upon the false and negligent misrepresentations and omissions made by Defendant, Plaintiff, and Plaintiff's healthcare providers were induced to and did use Advantage Fit, thereby causing Plaintiff to endure severe and permanent injuries.

210. Defendant knew and had reason to know that Plaintiff, Plaintiff's healthcare providers, and the general medical community did not have the ability to determine the true facts, which were intentionally and/or negligently concealed and misrepresented by Defendant.

211. Defendant had sole access to the material facts concerning the defective nature of Advantage Fit and its propensity to cause serious injuries.

212. At the time Defendant failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff was inserted with Advantage Fit, Plaintiff and her healthcare providers were unaware of Defendant's negligent misrepresentations and omissions.

213. Defendant failed to exercise ordinary care in making representations concerning Advantage Fit while it was involved in the drug's manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce because Defendant negligently misrepresented Advantage Fit's high risk of unreasonable and dangerous adverse side effects.

214. Defendant breached its duty to Plaintiff, her physicians, and the medical and healthcare community by representing that Advantage Fit has no serious side effects different from older generations of similar products or procedures.

215. Plaintiff and Plaintiff's healthcare providers reasonably relied upon the misrepresentations and omissions made by Defendant, where it concealed and misrepresented facts that were critical to understanding the true dangers inherent in the use of Advantage Fit.

216. Plaintiff and her healthcare providers would not have recommended and inserted Advantage Fit in Plaintiff had the true facts not been concealed by Defendant.

217. Plaintiff and Plaintiff's healthcare providers' reliance on the foregoing misrepresentations and omissions was the direct and proximate cause of Plaintiff's injuries.

218. Defendant knew, and had reason to know, that Advantage Fit had been insufficiently tested or had not been tested at all; that the products lacked adequate and accurate warnings; that it created a high risk, and/or higher than acceptable risk, and/or higher than reported risk that it represented a risk of adverse side effects, including pain and suffering, surgery to remove the product, and other severe and personal injuries, which are permanent and lasting in nature.

219. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

220. As a direct and proximate result of Defendant's negligent misrepresentations, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT IX
Breach of Express Warranty

221. Plaintiff realleges and incorporates by reference paragraphs 1 through 220 of this Complaint as if each were set forth fully and completely herein.

222. Through Defendant's public statements, descriptions, and promises regarding Advantage Fit, Defendant expressly warranted that each product was safe and fit for use by consumers, that it was of merchantable quality, that its side effects were minimal and comparable to other treatments for stress urinary incontinence, and that the products were adequately tested and fit for its intended use.

223. At relevant times, Defendant was aware that consumers, including Plaintiff, would use Advantage Fit, which is to say that Plaintiff was a foreseeable users of Advantage Fit.

224. Plaintiff and/or her inserting physicians were, at all relevant times, in privity with Defendant.

225. The Advantage Fit was expected to reach and did in fact reach its ultimate consumer, including Plaintiff and her inserting physicians, without substantial change in the condition in which it was manufactured and sold by Defendant.

226. Defendant breached various express warranties with respect to Advantage Fit, including the following particulars:

- a. Defendant represented to Plaintiff and her physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that Advantage Fit was safe, and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Advantage Fit;
- b. Defendant represented to Plaintiff and her physicians and healthcare providers that Advantage Fit was as safe and/or safer than other alternative procedures and treatments, and fraudulently concealed information that demonstrated that Advantage Fit was not safer than alternatives available; and

- c. Defendant represented to Plaintiff and her physicians and healthcare providers that Advantage Fit was more efficacious than other alternatives and fraudulently concealed information regarding the true efficacy of the product.

227. In reliance upon Defendant's express warranties, Plaintiff was inserted with Advantage Fit as prescribed and directed, and therefore, in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

228. At the time of making such express warranties, Defendant knew or should have known that Advantage Fit does not conform to these express representations because Advantage Fit was not safe and had numerous side effects, many of which Defendant did not accurately warn about, thus making Advantage Fit unreasonably unsafe for its intended purpose.

229. Members of the medical community, including physicians and other healthcare professionals, as well as Plaintiff and her physicians, relied upon the representations and warranties of Defendant in connection with the use, recommendation, description, and/or dispensing of Advantage Fit.

230. Defendant breached its express warranties to Plaintiff in that Advantage Fit was not of merchantable quality, safe, and/or fit for its intended uses, nor was it adequately tested.

231. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

232. As a direct and proximate result of Defendant's breach, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT X
Breach of Implied Warranty

233. Plaintiff realleges and incorporates by reference paragraphs 1 through 232 of this Complaint as if each were set forth fully and completely herein.

234. At relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold the Advantage Fit.

235. Plaintiff was a foreseeable users of the Advantage Fit.

236. At relevant times, Defendant intended that Advantage Fit be inserted for the purposes, and in the manner, that Plaintiff or her physicians or surgeons used it, and Defendant impliedly warranted each Advantage Fit to be of merchantable quality, safe and fit for such use, and to have been adequately tested.

237. Defendant was aware that consumers, including Plaintiff or her physicians or surgeons, would insert Advantage Fit in the manner described by the instructions for use and that Plaintiff was a foreseeable users of Advantage Fit.

238. Defendant knew or had reason to know that Plaintiff would rely on Defendant's judgment and skill in providing Advantage Fit for its intended use.

239. Plaintiff and/or her physicians and surgeons were at all relevant times in privity with Defendant.

240. Defendant's Advantage Fit was expected to reach and did in fact reach consumers, including Plaintiff and/or her physicians and surgeons, without substantial change in the condition in which it was manufactured and sold by Defendant.

241. Defendant breached various implied warranties with respect to Advantage Fit, including the following particulars:

- a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, medical

literature, and regulatory submissions that the Advantage Fit was safe, and fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Advantage Fit;

- b. Defendant represented that the Advantage Fit was safe and/or safer than other alternative treatments or procedures and fraudulently concealed information that demonstrated that Advantage Fit was not as safe or safer than alternatives; and
- c. Defendant represented that the Advantage Fit was more efficacious than other alternative treatments and fraudulently concealed information regarding the true efficacy of the Advantage Fit.

242. In reliance upon Defendant's implied warranties, Plaintiff and/or her inserting physicians and surgeons used the Advantage Fit as prescribed in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

243. Defendant breached its implied warranties to Plaintiff and/or her inserting physicians and surgeons in that Advantage Fit was not of merchantable quality, safe, and fit for its intended use, or adequately tested, in violation of common law principles.

244. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

245. As a direct and proximate result of Defendant's breach, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT XI
Violation of Consumer Protection Laws

246. Plaintiff realleges and incorporates by reference paragraphs 1 through 245 of this Complaint as if each were set forth fully and completely herein.

247. Plaintiff purchased and used Advantage Fit primarily for personal use, thereby suffering ascertainable losses from Defendant's actions in violation of consumer protection laws.

248. Had Defendant not engaged in the deceptive conduct described herein, Plaintiff and her physicians would not have purchased and/or paid for Advantage Fit and would not have incurred related medical costs and injury.

249. Defendant engaged in wrongful conduct while at the same time obtaining, under false pretenses, moneys from Plaintiff for Advantage Fit that was inserted into Plaintiff and that would not have been paid had Defendant not engaged in unfair and deceptive conduct.

250. Unfair methods of competition or deceptive acts or practices that were proscribed by law include the following:

- a. Representing that goods or services have characteristics, ingredients, uses, benefits, or quantities that it does not have;
- b. Advertising goods or services with the intent not to sell them as advertised; and
- c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion and/or misunderstanding.

251. Plaintiff was injured by the cumulative and indivisible nature of Defendant's conduct. The cumulative effect of Defendant's conduct directed at patients, physicians, and consumers, including Plaintiff and her physicians, was to create demand for and promote the sale of Advantage Fit. Each aspect of Defendant's conduct combined to artificially create sales of Advantage Fit.

252. Defendant has a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of Advantage Fit.

253. Had Defendant not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for Advantage Fit and would not have incurred related medical costs.

254. Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers, including Plaintiff and her physicians, constituted unfair and deceptive acts and trade practices in violation of state and federal consumer protection statutes.

255. Defendant's actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or trade practices in violation of state and federal consumer protection statutes.

256. Defendant has engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of state and federal consumer protection statutes, which serve to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising. Defendant is the supplier, manufacturer, advertiser, and seller who is subject to liability under such legislation for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

257. Defendant violated the statutes that were enacted to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising by knowingly and falsely representing that Advantage Fit was fit to be used for the purpose for which it was intended, when in fact it was defective and dangerous, and by other acts alleged herein. These representations were made in uniform promotional materials and product labeling.

258. Defendant's deceptive, unconscionable, unfair and/or fraudulent misrepresentations and material omissions to Plaintiff constituted consumer fraud and/or unfair

and deceptive acts and trade practices in violation of consumer protection statutes, including but not limited to O.C.G.A. §§ 10-1-372 et seq.

259. The actions and omissions of Defendant alleged herein are uncured or incurable deceptive acts under the statutes enacted in the states to protect consumers against unfair, deceptive, fraudulent, and unconscionable trade and business practices and false advertising.

260. Defendant had actual knowledge of the defective and dangerous condition of Advantage Fit and failed to take any action to cure such defective and dangerous condition.

261. Plaintiff and her inserting physicians and surgeons relied upon Defendant's misrepresentations and omissions in determining which product to use and/or procedure to undergo and/or perform.

262. Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians, and consumers constitute unfair and deceptive acts and practices.

263. By reason of the unlawful acts engaged in by Defendant, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

264. Defendant's conduct was a substantial factor in causing Plaintiff's injuries.

265. As a direct and proximate result of Defendant's violation of the consumer protection statutes, Plaintiff has been injured, suffered severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, loss of comfort, and economic damages, including but not limited to past and future medical expenses, lost income, and other damages. Plaintiff may also require additional medical and/or hospital care, attention, and services in the future.

WHEREFORE, Plaintiff respectfully request this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees and all such other and further relief as this Court deems just and proper.

COUNT XII
Punitive (Exemplary) Damages

266. Plaintiff realleges and incorporates by reference paragraphs 1 through 265 of this Complaint as if each were set forth fully and completely herein.

267. Pursuant to O.C.G.A. § 51-12-5.1, Boston Scientific is, thus, liable to Plaintiff for punitive (exemplary) damages in an amount to be determined by the enlightened conscience of the jury, based on the clear and convincing evidence to be presented at trial, in an amount sufficient to deter Boston Scientific and others from future similar conduct.

PRAYER FOR RELIEF

WHEREFORE, Petitioner demands trial by jury, and pray for judgment against Defendant as follows:

1. A judgment against Defendant holding it liable for compensatory damages in a reasonable amount determined to be fair and just by the jury in this cause sufficient to adequately compensate Petitioner for her harms and losses, including but not limited to damages:
 - a. For past and future general damages, the exact amount of which has yet to be ascertained, in an amount which will conform to proof at time of trial;
 - b. For past and future economic and special damages, according to proof at the time of trial;
 - c. For past and future medical and incidental expenses, according to proof at the time of trial;

- d. For past and future loss of earnings and impaired earning capacity, according to proof at the time of trial;
 - e. For past and future physical impairment;
 - f. For past and future physical disfigurement; and
 - g. For past and future pain and suffering, as well as mental and emotional distress, according to proof at the time of trial.
- 2. For punitive (exemplary) damages;
 - 3. For costs, attorneys' fees, interest, or any other relief, monetary or equitable, to which she is entitled; and
 - 4. For such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Petitioner hereby demands trial by jury as to all issues in the above captioned matter.

This 28th day of July, 2022

Respectfully submitted,

SCHNEIDER HAMMERS

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